EXHIBIT C

UNITED STATES DISTRICT COURT

DISTRICT OF MINNESOTA

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In Re:

Bair Hugger Forced Air Warming

Products Liability Litigation

This Document Relates To:

All Actions MDL No. 15-2666 (JNE/FLM)

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DEPOSITION OF ALEXANDER A. HANNENBERG

VOLUME I, PAGES 1 - 306

AUGUST 8, 2017

(The following is the deposition of ALEXANDER A. HANNENBERG, taken pursuant to Notice of Taking Deposition, via videotape, at the Aloft Boston Seaport Hotel, 401-403 D Street, Boston, Massachusetts, commencing at approximately 9:16 o'clock a.m., August 8, 2017.)

P R O C E E D I N G S

(Witness sworn.)

ALEXANDER A. HANNENBERG

called as a witness, being first duly sworn, was examined and testified as follows:

ADVERSE EXAMINATION

BY MR. ASSAAD:

Q. Please state your name.

A. Alexander Hannenberg.

Q. You may need to speak up a little bit.

A. Okay.

Q. My name's Gabriel Assaad and I represent thousands of plaintiffs in the multidistrict litigation. I'm here to ask you numerous questions regarding your expert opinions today. Do you understand that?

A. Yes, I do.

Q. Okay. Have you had your deposition taken before?

A. Yes.

Q. Approximately how many times?

A. Once.

Q. And was that a medical malpractice case?

A. It was.

Q. And what were the allegations in that case?

No, only -- only in this matter, in which case I guess I consult for the law firm.

Q. Do you -- do you know anyone at -- that works for 3M?

A. I don't believe so, no.

Q. Okay.

(Exhibit 1 was marked for identification.)

BY MR. ASSAAD:

Q. Have you ever been --

Before I talk about Exhibit 1, have you ever been -- or done any research that was funded by 3M?

A. No.

Q. Okay. Do you know Scott Augustine?

A. I have met him.

Q. How long ago?

A. More than five years ago.

Q. Okay. You just met him once?

A. I believe so.

Q. Did you have a conversation with him?

A. Yes.

Q. And what was the conversation about?

A. It was about the content of a scientific panel at the anesthesia annual meeting at which I had presented. He approached me at the end of the -- end

incomplete?

A. Yes, I did.

Q. Okay.

(Exhibit 2 was marked for identification.)

BY MR. ASSAAD:

Q. I'm still on Exhibit 1. With respect to Exhibit 1, are all the materials that you considered, do you consider them authoritative?

A. What do you mean by "authoritative?"

Q. Reliable.

A. No. There are -- there are some items in this report who -- that offers conclusions I'm not sure are valid.

Q. Okay. This is just stuff that you've considered; correct?

A. Yes.

Q. And is this --

And what's been marked as Exhibit 2 is a document that was provided to plaintiffs' counsel this morning that is titled "Materials Considered;" correct?

A. Yes.

Q. Okay. And this is different than Exhibit 1; correct?

Q. Okay. Is it fair to say that these four items, which are Legg, Wood, Melling and Scott, are not cited in your expert report?

A. It's easy enough to check if I can see my expert report.

(Exhibit 3 was marked for identification.)

A. That is correct, they are not cited.

Q. Okay. You've been asked to be an expert in this case; correct?

A. Yes.

Q. And you agree that an expert should be -- should be objective; correct?

A. Yes.

Q. Should not be an advocate for either side; correct?

A. Yes.

Q. Should be accurate; --

A. Yes.

Q. -- correct?

So I'm trying to understand what was it yesterday that made you think of these four documents.

A. I was ref -- reflecting on the conversation that we were going to have today and realized that my thinking about the matter at hand was informed by

material other than those that were on the Materials Considered list.

Q. Okay. Did you review any depositions?

A. Did I --

Yes, I reviewed depositions.

Q. That's not on Exhibit 2; correct?

A. That is on --

I'm sorry, I -- I -- I stand corrected. The expert reports.

Q. So you haven't looked at any depositions?

A. Have I looked at any dep --

Hon -- honestly, to make a distinction between the depositions and the expert reports, I'm not totally clear on --

Q. You don't know what a deposition is?

A. I know what a deposition is, but when I think -- think about the opinions of those who have been deposed and those who have submitted expert reports, in my mind I'm not clear on in what format I considered the material from those individuals.

Q. So sitting here today you don't know what depositions you reviewed, if any.

A. I believe I have reviewed depositions. Which ones, and which ones I relied on the expert reports, I'm not able to say.

A. I don't know.

Q. You don't know.

A. I don't -- I -- I -- I don't know. As I said, the -- my impression -- my impressions are related to the content, not so much the format; that is to say, if an individual is deposed and offered an expert opinion, whether I reviewed their expert opinion or the deposition is hazy in my mind as I sit here today.

Q. Let's -- maybe we can make it sim -- be simplified. Did you rely on anything you read in the depositions in formulating your opinions?

A. That -- that is possible.

Q. Well I don't want "possible," I want to know one way or the other.

A. Okay. I am unable to tell -- to tell you what I was --

What I've been saying is that I've reviewed materials in various -- in various formats from various sources. My -- whatever opinion I hold -- hold today is the result of the sum of that information, and I have not really made an effort to connect an opinion with whether it is directly derived from a particular document.

Q. So if I understand --

counsel.

Q. Okay. So Jarvis and Stonnington.

A. The video that we discussed was provided to me by counsel.

Q. Anything else?

A. A test -- testing report on filters.

Q. Is that listed in Exhibit 2?

A. No, it is not.

Q. Why not?

A. Because I hadn't thought of it at the time I created Exhibit -- Exhibit 2.

Q. As of yesterday.

A. Correct.

Q. Okay. What else?

A. I can't say.

Q. When did you receive the depositions?

A. In the last several months.

Q. Did you receive the deposition of Al Van Duren?

A. I'm sorry?

Q. Al Van Duren. Do you know who he is?

A. Al Van -- Al Van Duren. Al Van Duren, that name sounds -- that sounds familiar. And again, whether the name sounds familiar because of seeing a paper of his, whether he was referenced in the expert

reports that I did -- did read -- read, I don't know, but the name sounds -- sounds familiar.

Q. Did you read his deposition? Simple "yes" or "no" or "I don't know."

A. I don't know.

Q. Okay. Did you read the deposition of Dr. Wenzel?

A. No.

Q. Did you read the deposition of Dr. Kuehn?

A. No. I believe I read their expert reports.

Q. Did you read the deposition of Dr. Mont?

A. I don't know.

Q. Okay. Can you tell me any dep -- any deposition that you've read from what subject matter it was dealing with, if it was a doctor, anything today?

A. I read -- I read parts of Dr. Kurz.

Q. Kurz?

A. Yes.

Q. Who is Dr. Kurz?

A. Dr. Andrea Kurz is a scientist and the author of an important paper in the area of surgical normothermia.

Q. Are you talking about the 1996 paper on thermoregulation --

A. Yes.
Q. -- and infection, surgical-site infection?
A. Yes.
Q. Do you consider her an expert in the field?
A. I consider her an expert in the field.
Q. Do you consider Dr. Sessler an expert in the field?
A. Yes.
Q. Have they done more research on normothermia than you have?
A. Yes.
Q. In fact, you have done no research on normothermia; have you?
A. Correct, except to the extent that I have to make decisions about how I manage the temperature of the patients I anesthetize.
Q. Let me ask my question again. And this is going to go a lot quicker if you answer my question. Okay?

I understand you're a treating physician. I understand what anesthesiologists do. We don't need to go there. My question is you, Dr. Hannenberg, have not done any research on normothermia; correct?
A. Well are you -- are you talking about laboratory re -- research, clinical studies, or are

you talking about re -- research in the sense of evaluating the available science in order to make a clinical decision?

Q. I'm --

Let's talk about clinical studies. Have you done any clinical studies?

A. No.

Q. Have you done any laboratory research?

A. No.

Q. Okay. You've read papers; correct?

A. Correct.

Q. Okay. And some of the papers we'll be talking about today; correct?

A. Yes.

Q. But you haven't done what Dr. Kurz or Dr. Sessler has done; correct?

A. Correct.

Q. Or any other people out in -- in -- who have published papers on normothermia; correct?

A. Correct. Other than an edit -- an editorial on the subject of surgical normothermia, I have not published on this subject.

Q. And you read the paper of Dr. Sessler; correct?

A. Correct.

Q. And how do you know Dr. Sessler?

A. Dr. Sessler and I served on a committee that developed a performance measure on perioperative normothermia.

Q. Okay. So we're going to get to that, but I just want to understand what is the universe of information you used to formulate your opinions, and my understanding right now is Exhibit 2, Dr. Wenzel, Dr. Kuehn and Dr. Mont's expert reports, a video of airflow, a testing report regarding filtration, and parts of Dr. Kurz's deposition; correct?

MS. LEWIS: Object to the form of the question.

A. Those materials did serve as the basis for my opinions, --

Q. Anything else?

A. -- but I think I've already out -- outlined the fact that I have seen trade press publications, --

Q. Which ones?

A. -- an e-mail --

I -- I cannot -- I cannot cite -- cite them. I haven't kept a record of those publications that I've seen over the course of a decade.

Q. But did you use them and look at them in creating Exhibit 3, your expert report?

A. With respect to what is in my expert report, my expert report has the citations of the materials that I point to in the text of the expert report. So the content of the expert rep -- report is one -- is one thing, the full range of my opinions on the sub -- on the subject is something else.

Q. Okay. But with respect to all the materials you used in formulating the opinions in your Exhibit -- in Exhibit 3, your -- your expert report, we've discussed those today; correct?

A. I'm -- I'm sorry. Say again.

Q. With respect to Exhibit 3, --

A. Yes.

Q. -- we have discussed all the materials that you have reviewed or looked at or considered in formulating your opinions that are in Exhibit 3, your expert report; correct?

A. Yes.

Q. Okay. I understand you have education, training and experience, but I'm talking about documents that you've looked at or considered. You understand that; correct?

A. Yes.

Q. Okay. Did you look at the Huang paper?

A. If you can show it to me I can --

Q. Well it's not listed here, so if it's not listed in Exhibit 2, have you -- did you look at it or consider it in formulating your opinion for your expert report?

A. No.

Q. What about the Zink paper?

A. I --

No, it did not factor into my expert report.

Q. What about the Moretti paper?

A. I probably have seen -- have seen it, but I would not say that it is part of the content of my expert report.

Q. What about the Sun paper. Do you know what the Sun paper is?

A. No.

Q. Okay. Sun with -- with Andrea Kurz, do you know what paper that is?

A. No.

Q. Okay. What about the Sessler/Olmstead/Kuplinger paper, do you know what paper that is?

A. No.

Q. Okay. What about Belani, does that name sound familiar?

A. Yes, it does.

Q. Did you review that paper?

A. I prob -- I probably did.

Q. Did you review that paper in formulating your opinions in Exhibit 3?

A. No.

Q. What about the Reed paper, "Evaluation of Intake Filtration: Internal Microbial Buildup in Airborne Contamination Emissions," did you review that paper in formulating your opinions in Exhibit 3?

A. No.

Q. You added Legg, Cannon, Hamer, "Do forced air patient-warming devices disrupt unidirectional downward airflow?" Did you look at any other Legg paper in formulating your opinions on Exhibit 3?

A. No.

Q. Okay. Did you find this Legg paper on your own or did -- was that provided to you by counsel?

A. That was, I believe, provided to me -- to me by stopsurgicalinfections.org.

Q. Okay. Did you review the Desari paper, "Effect of forced-air warming on the performance of operating theatre laminar flow ventilation?"

A. Yes, I think I did.

Q. In formulating your opinions in -- in Exhibit 3?

A. Well in -- in Ex -- in Exhibit 3 I address

the proposition that forced-air warming devices disrupt laminar -- laminar flow. There are multiple sources of that proposition; I believe that is one -- is one of them. So that I was -- did not refer specifically to that paper but to the -- the opinion about forced-air warming and laminar flow --

Q. Does the Desari paper --

A. -- more generally.

Q. Does the Desari paper have to be included --

MS. LEWIS: Wait. Did you finish your answer?

THE WITNESS: Yes.

Q. Does the Desari paper have to be included in Exhibit 2 now? Would you include it?

A. I -- I -- I don't -- I don't see why not.

Q. Okay. So it should be another document -- a document that you considered in formulating your opinions of Exhibit 3?

A. Yes.

Q. Okay. So do you recall the paper written by Sessler, "Forced-air warming does not worsen air quality in laminar flow operating rooms?" Did you ever read that paper?

A. I recall -- I recall the title. Whether

I've read it or not, I don't know.

Q. Okay. So you didn't -- you didn't consider that paper in formulating your opinions in Exhibit 3; correct?

A. Correct.

Q. Okay. Do you recall reading the paper by Belani, "Patient warming excess heat: The effects on orthopedic operating room ventilation performance?"

A. No.

Q. Do you know who Dr. Belani is?

A. No.

Q. He was -- he was the Chair of Anesthesiology at the University of Minnesota.

A. No.

Q. Did you read the Stocks paper on particles?

A. Did I read the Stocks paper? I don't recall.

Q. What about the Darouiche paper on particles and bacterial load?

A. No.

Q. I understand that on Exhibit 2 you looked at the letter to the editor -- well strike that.

Did you read the Albrecht paper, "Forced air warming: A source of airborne contamination in the operating room?"

A. I believe I did.

Q. Okay. But you didn't put that in something that you considered in your ex -- for your expert report; correct?

A. Correct.

Q. Let -- let me ask you a question. Exhibit 2 is not in alphabetical order; correct?

A. Correct.

Q. So why would you stick four more items in the middle -- or not even in the middle, like randomly into Exhibit 2 and just -- instead of putting it at the end to make it easy for everyone to know what you added to your -- your Materials Considered?

A. That's where the curs -- cursor was -- was when I pulled the citation.

Q. Yeah. But then you -- you went from Melling to Scott and you jumped over Leitjens, so it's not like you continued writing four -- four directly in a row.

A. Well --

Q. I mean you put Legg, Wood, then you skipped -- then you -- then you put your cursor again and you went to Melling and you moved your cursor again and went to Scott. Why would you do that?

A. In order to look at what was already in

MS. LEWIS: Object to the form.

A. I don't know that he says that -- that he says that publicly, but I've just told you what my opinion about patient warming is.

Q. Have you ever seen Dr. Sessler lecture on maintaining normothermia?

A. I -- I am sure I have. I can't recall when and where.

Q. So sitting here today, you don't remember.

A. Correct.

Q. Okay. Have you --

When was the last time you took a CLE on maintaining -- or CME on maintaining normothermia, if any?

A. I can't -- I can't recall taking a CME specifically on that subject.

Q. When is the last time you've attended any lecture -- CME, talk, anything -- on maintaining normothermia?

A. I don't -- I don't -- I don't recall.

Q. When was the last time you went to the ASA conference?

A. Last October.

Q. Okay. With respect to Exhibit 2, is this something that you drafted?

A. Yes.

Q. Okay. Did you ever review the deposition of Dr. Sessler?

A. I have reviewed a deposition of Dr. Sessler.

Q. Okay. Why wasn't that included in Exhibit 2?

A. Because I can't identi -- identify what content of that deposition informed my opinion.

Q. Exhibit 2 says "Materials Considered;" correct?

A. Yes.

Q. Correct?

A. Yes.

Q. It doesn't say "Materials Relied Upon;" correct?

A. Correct.

Q. Okay. So now we have Dr. Sessler's deposition. When did you review his deposition?

A. I don't recall.

Q. This year?

A. Most probably.

Q. Okay. Have you reviewed the deposition of Gary Maharaj?

A. No.

Q. Have you reviewed the deposition of --

ever --

Have you ever reviewed the deposition of Teri Sides?

A. No.

Q. Have you ever reviewed the deposition of Karl Zgoda?

A. No.

Q. Have you ever reviewed the deposition of Gary Hansen?

A. No, I don't think so.

Q. Have you ever reviewed the deposition of Troy Bergstrom?

A. No.

Q. Have you ever reviewed the deposition of Gary Maharaj?

A. I don't recall.

Q. Okay. Have you ever reviewed the deposition of Dave Westlin?

A. No.

Q. Have you ever reviewed the deposition of Dr. Elghabashi?

A. No.

Q. Do you know who Dr. Elghabashi is?

A. No.

Q. What about Mike Buck?

A. No.
Q. Do you know who Mike Buck is?
A. No.
Q. What about Dan Koenigshofer?
A. Other than the name sounding familiar, no.
Q. What about --
Did you review the deposition of Dr. Jarvis?
A. I don't believe I read his deposition. I --
Q. Have you read the deposition of Dr. Stonnington?
A. No. I read -- I read their expert reports.
Q. I understand that. I -- I know that's on Exhibit 2.
A. Yes.
Q. I'm asking about depositions.
A. Yes.
Q. Have you reviewed any medical records in this case?
A. In this case. In this case.
Q. Yes.
A. I reviewed medical records of Walton and Johnson.
Q. Okay. But you haven't reviewed any of the -- the upcoming trials and the medical records of those cases.

I don't understand that question.

Q. I mean did he give you --

Did he coach you on how to become an expert witness and how to answer questions, defense counsel?

A. Yes.

Q. Okay. What did he tell you?

A. To ans -- answer truthfully and completely and to be sure I understood the question.

Q. Okay. I mean as a doctor you take a lot of notes, don't you, in your practice?

A. Yes.

Q. Okay. Because that's how you can keep track of what you did and -- and what was done in the past; correct?

A. Correct.

Q. Okay. And not only do you take notes, but every other doctor takes notes and nurses take notes. It's just general practice to take notes; correct?

A. Correct.

Q. And there's actually a section that says "Progress Notes" in most medical records; correct?

A. Correct.

Q. But for acting as an expert, you don't take notes.

A. Correct.

Q. Okay. Is there something you're trying to hide?

A. No.

Q. Okay. Then why not take notes?

A. Because I was advised by counsel not to.

Q. Okay. I mean if you took notes about what you reviewed, then we would have a list of what you reviewed in this case; correct?

A. Presumably.

Q. You think we'd have a more accurate picture of what you reviewed?

A. We might.

Q. We might or most likely we would?

A. We -- we would have an additional resource to -- to consult.

Q. Well you don't even remember the depositions you've read; correct?

A. Correct.

Q. If you took notes as to what depositions you read, we'd have a record of what you read; correct?

A. Correct.

Q. And if you took notes of what documents you reviewed, we'd have all the documents that you reviewed; correct?

A. Correct.

Q. Okay. Note-taking is a good thing; isn't it?

A. I have been told that in this context it is not -- it is not.

Q. By defense attorneys?

A. Correct.

Q. Okay. I mean you teach your residents to take notes; correct?

A. I don't teach -- I don't teach residents now, but when I did -- when I did, yes.

Q. Yeah. I mean it would be almost malpractice if you didn't take notes; correct?

A. I'm not sure what medical practice and medical malpractice has to -- has to do with conduct as an expert wit -- expert witness, but it is certainly standard practice among physicians to make notes.

Q. I mean you -- you understand that there's almost 3,000 people that have filed cases in this litigation. Are you aware of that?

A. I'm aware of that.

Q. Okay. That's 3,000 people that had severe periprosthetic joint infections. Do you understand that?

MS. LEWIS: Object to the form.

Q. Going back to Exhibit No. 2, I don't see any internal 3M documents that you reviewed. Have you ever reviewed any internal 3M documents in formulating your opinions?

A. I don't recall that I have.

Q. Well if it's not listed in Exhibit 2, that means you never reviewed any internal 3M document, correct, in formulating your opinions?

A. In formulating my opinions, that's -- that's correct.

Q. So you have reviewed internal 3M documents?

A. I -- I don't -- I -- I just said I didn't recall whether I had or not, but if I -- if I did, they were not material to creating my opinions.

Q. But you considered them.

A. I'm not sure what -- I --

So some things I may consider and dismiss as not important in creating an opin -- an opinion on a matter, so it's -- so I'm not -- I'm not sure whether that counts as considered in -- in your view or in the context of your question.

Q. Well you -- you saw --

You mentioned there was a filtration study that you looked at; correct?

A. Correct.

Q. Okay. And it was an internal 3M document?
A. I don't -- I don't know whether it was or -- was or not.
Q. You don't know?
A. I don't know.
Q. Do you have it here with you today?
A. No, I don't.
Q. Did you bring anything with you today?
A. No.
Q. Do you think if you brought your documents you would be able -- you brought your documents you would be able to answer these questions?
A. If I looked at that particular document, it might tell me whether it was an internal 3M document or not, but I don't know that for sure.
Q. Have you ever done a case study as a doctor?
A. I'm not sure what you mean by "a case study."
Q. Like where you talk about a patient in front of a bunch of students.
A. Yes.
Q. Okay. Do you go into the case study and discuss with your students about the case without any of the medical records?
A. Seldom.

A. Safety is paramount with respect to patients.

Q. And physicians should do everything -- strike that.

Do you have any experience designing a medical device?

A. Many -- many years ago I began the process -- and quickly abandoned it -- of developing a tooth guard, a tooth guard for intubation, but it was -- the design was never completed. It was never brought to market or patented. So that is the limit of my experience.

Q. Do you have any patents?

A. No.

Q. Have you ever dealt with the FDA?

A. Have I ever dealt with the --

Q. With a medical device issue or --

A. No.

Q. Okay. You mention in your expert report that you've acted as an anesthesiologist on approximately 400 total joint arthroplasties. Does that sound about right?

A. Yes, it does.

Q. And that's over your career of -- since 1983?

Q. Now in looking at Exhibit 5, can you direct me to any article in which you have discussed thermoregulation?

A. I think the only -- the only one is Anesthesia & Analgesia in 2008.

Q. 2008. Was it a peer-reviewed article?

A. It's an invited editorial.

Q. Is it under "PUBLICATIONS?"

A. Yes. Page 15, about halfway down.

Q. Okay. And that was an editorial that you wrote with Sessler -- Dr. Sessler.

A. Yes.

Q. And it wasn't peer-reviewed; correct?

A. Correct.

Q. Okay. Because it was an editorial.

A. Correct.

Q. Okay. And that really had nothing to do with the science of maintaining normothermia, it was more with the -- with the -- whatchumacallit -- the -- I'll get the right word in a second -- pay for performance; correct?

A. Correct.

Q. Would you agree with me that most of your talks and literature deal with pay for performance or the economics of anesthesiology?

A. I -- I haven't done the math, but I have spoken frequently on those subjects.

Q. I mean let's go through your -- your talks starting on page six.

Oh, before I get there, what is this medical malpractice committee that you're on?

A. Committee?

Q. Yes. Hold on. The Massachusetts --

A. Medical malpractice tribunal?

Q. Yes.

A. The law in Massachusetts requires that medical malpractice cases be heard by a three-member tri -- tribunal before they're allowed to go -- allowed to go forward. The three-member tribunal is constituted by a physician, a judge, and an attorney. I think there is a requirement that it be a physician of the same specialty. So from time to time over many years -- although not recently -- I've been asked to serve on those -- those tribunals as the anesthesiologist member.

Q. When -- when -- when a -- someone wants to sue an anesthesiologist?

A. Yes.

Q. How many times did you sit on the panel?

A. Probably eight or 10, roughly.

numerous times in your CV. What is relative value with respect to anesthesiology?

A. Relative value refers to a -- a -- a payment system of aligning different physician services according to their relative value. The relative val -- value itself reflects three components: the physician work involved, the practice expenses involved, and the cost of professional liability insurance for those providing that service.

Q. And would it be fair to say that a lot of your work done in the past dealt with trying to educate and work to increase the payments made to anesthesiologists?

A. Yes.

Q. Okay. So in other words, a lot of your lectures dealt with the money.

A. They dealt with the relative value payment system.

Q. The money.

A. Okay.

Q. All right. Again today it's about the money; right?

A. If you say.

Q. I'm asking what you say. I mean we could go one by one and I could go and ask you, but a lot of it

has to do with the money.

A. Sure.

Q. Okay.

A. Yeah.

Q. Like, for example, number one on page six, invited lecture, presentation, "Anesthes -- Anesthesia Reimbursement...;" correct?

A. Yes.

Q. That's about the money; correct?

A. It's about the mon -- money and the methodology underlying the money.

Q. Okay. Next one, "Basics of Anesthesia Economics," that's about the money as well; correct?

A. Yes.

Q. Next one, "Basics of an Anesthesia Agreement," that's about creating agreements with hospitals to make more money; correct?

A. It's not about agreements with hospital -- with hospitals, it's about agreements with payers.

Q. With payers.

I mean it's about how to get paid the most for your services; correct?

A. It's about how to get -- get paid an equitable amount for our services.

Q. "The Changing Business of Anesthesia,"

that's about the economics of anesthesia; correct?

A. Yes.

Q. "The Economics of Private Practice" again is about the economics of anesthesia and how to increase your profits; correct?

A. The -- that is --

That one is not so much about increasing your profits, it's more methodological, it -- it being a presentation for residents.

Q. I mean the next two down, "Ins and Outs of Anesthesia Reimbursements," that's about the money; correct?

A. It is about the method of payments from payers to anesthesiology practices, from anesthesiology practices to the employees of those practices, so it is financially oriented.

Q. It's about the money; correct?

A. Yes.

Q. Okay. Two more down, "The Perils of RBRVS Payment in Anesthesia." What's RBRVS?

A. Resource Based Relative Value System.

Q. So it's about the money; correct?

A. Yes.

Q. "The Perils of Medicare RBRVS," that's about the money; correct?

A. Yes.

Q. And then "Anesthesia and Medicare," that's also about reimbursement from Medicare; correct?

A. Yes.

Q. It's about the money; correct?

Yes?

A. Yes.

Q. Okay. "Basics of Anesthesia Reimbursement," that's also about the money; correct?

A. Yes.

Q. "Emerging Trends in Reimbursement...," that's about the money, correct?

A. Yes.

Q. Let's go a couple down, "Analyzing the Profitability of Anesthesia Fee Schedules," that's about the money; correct?

A. Yes.

Q. "New Trends in Anesthesia Reimbursement," that's about the money; correct?

A. Yes.

Q. Okay. So you agree that most of these are about the money; correct?

A. Yes.

Q. Okay. Very little science, scientific research, all about the money; correct?

A. Yes.

MS. LEWIS: Objection to form.

Q. In fact, there's very little scientific research in these invited presentations; correct?

A. In that -- in that period of time, yes.

Q. We go to page seven, number two, "Commercial Payments Based on the Medicare Fee Schedule," that's about the money; correct?

A. Yes.

Q. Next one, "Introduction to Anesthesia Economics," that's about the money; correct?

A. Yes.

Q. I mean I --

Almost every single one of these is something to do about the money; correct?

A. In that period of time, yes.

Q. Okay. So would you agree with me that most if not all invited lectures on page seven is about the money?

A. On page seven?

Q. Yes.

A. Sure.

Q. Okay. Let's go to page eight. Number two, "Medicare Forecast 2004," that's about the money; correct?

A. Yes.

Q. "Anesthesia Reimbursement...," that's about the money; correct?

A. Yes.

Q. "Payment for MAC and Conscious Sedation," that's about the money; correct?

A. Yes.

Q. "Coding and Compliance Considerations in Monitored Anesthesia Care," that's about the money; correct?

A. Yes.

Q. "Professional Fees and Other Departmental Financial Support," that's about the money; correct?

A. Yes.

Q. "Anesthesia Economics...," that's about the money; correct?

A. Yes.

Q. Okay. You agree with me that most if not all on page eight are invited lec -- presentations about the money?

A. Yes.

Q. Okay. Let's go to page nine. First one, "Perioperative Temperature Management," 2005, is that about the money?

A. No.

Q. Was it not --
Wasn't part of that pay for performance?
A. A part of that lecture? No.
Q. Are you sure about that?
A. Yes.
Q. Okay. Is that the one where you saw Dr. Scott Augustine?
A. No.
Q. Okay. But the next one is "Pay For Performance...;" correct?
A. Correct.
Q. That's about the money.
A. Yes.
Q. "The Hospital Stipend Goldrush," that is about the money?
A. Yes.
Q. "Pay For Performance...," next one, is that about the money?
A. In part.
Q. Okay. And the next two or three are about pay for performance; correct?
A. In part.
Q. Okay. You have "Malignant Hypo -- Hyperthermia;" correct?
A. Yes.

Q. That's not any --

That doesn't deal with any issues in this case; correct?

A. Correct.

Q. All right. Would you agree with me that except for one or two on page nine, that most of these invited presentations are about the money?

A. Yes.

Q. Okay. And also the politics to -- to -- to deal with reimbursement; correct?

A. What are you referencing?

Q. "Science, Politics, Press and Money."

A. That is about the activities of the American Society.

Q. Of --

A. Anesthesiologists.

Q. -- anesthesiologists; correct?

A. Yes.

Q. Which at one time you were the president; correct?

A. Correct.

Q. And it's a -- and it has -- it's a lobb --

They have a lobbying group; correct?

A. Yes.

Q. Okay. And you donate to the lobbying group

for the ASA; correct?

A. Correct.

Q. Okay. So page 10, first one, "Pay For Performance and the Anesthesiologist," that's about the money; correct?

A. It's about the mon -- money, but like all the discussions of pay for performance, it is about managing clinical care to meet the pay-for-performance standards, so it's both about the mon -- money and clinical be -- and clinical behavior.

Q. Now pay for performance is where you get additional money for certain measures; correct?

A. For certain measures.

Q. They don't deduct money from you; correct?

A. Well it depends when, when you're -- when you're talking about, because in the current program, yes, they -- yes, they do deduct money -- deduct money.

Q. Okay. But during this time, pay for performance in 2017, it would add additional money; correct?

A. Correct.

Q. Okay.

A. Correct, for those physicians who achieved the benchmarks established in the pay-for-performance

program.

Q. When did they start -- when did they start deducting money for not meeting the pay-for-performance standards?

A. Well they --

Based on this year's performance, they will deduct mon -- money in the 2019 payments, so there's a two-year-cycle lag.

Q. Oh. And how long has that been going on?

A. This year.

Q. This is the first time this year they're doing that?

A. Correct.

Q. Okay. So up until 2017, pay for performance was additional money to meet certain outcomes.

A. Certain outcomes or re -- or reporting standards.

Q. Reporting standards. Okay.

So let's go to page 10. You have "The Hospital Stipend Goldrush." That's about the money; correct?

A. Correct.

Q. "The Future of Anesthesia Practice...," that's about the money; correct?

A. I don't recall the content of that.

Q. "Pay For Performance...," that's about the money; correct?

A. As I have said before, it's about the -- the money and the clinical practice required.

Q. It has a money component.

A. It has a money component.

Q. Okay. Let's go down. "Medicare Reform, Quality and Pay For Performance," that has to do with money; correct?

A. That has something to do with the money.

Q. Would you agree with me that most on page 10 is dealing with the money issues and practice issues of anesthesiology?

A. Yes.

Q. Okay. Nothing scientific on -- on page 10; correct?

A. That's right.

Q. Okay. No research on page 10; correct?

A. In the sense that I was not presenting my original research -- research, that is -- that is true.

Q. And when I say "research," I'm talking about scientific research dealing with patient care.

A. Well the curr --

The pay-for-performance standards are

grounded in scientific -- in scientific research, so in that -- in that sense it is not devoid of -- of science.

Q. I guess my question is: No research with respect to like clinical studies or research on patient care, it was more of how certain standards and pay for performance were going to be met.

A. In explain -- in explaining what the pay-for-performance standards are -- are, particularly with respect to process measures; that is, a standard for a particular activity of care, explaining the science that links that activity and care -- care to a patient outcome is based on scientific studies. So frequently, in describing the pay-for-performance stan -- standards, it would be important to explain why do we have this measure about perioperative temperature, for example, and what is the link -- linkage between warming a patient and an important outcome, why do we have -- why do we have a measure on this, and to some extent the editorial that we talked about a moment ago was meant to answer -- answer that question. But in all of the pay-for-performance talks that you have been referencing, that was, in most instances, a component of the presentation.

Q. But you're referencing articles, you're not

discuss --

You're referencing research articles, you're not presenting research articles; correct?

A. I don't understand the difference between --

Q. For example --

A. -- referencing and presenting --

Q. Okay.

A. -- a research article.

Q. Well -- well, for example, I'm Andrea Kurz and I just came out with my 1996 study, "I'm going to talk about it, and here's my study and this is the basis of my study." That's presenting a research paper; correct?

A. That's presenting my own research paper.

Q. Yes.

A. Is that the distinction you're trying to make?

Q. Yes, or -- yes, or compared to --

A. Okay. Correct.

Q. -- "Hey, we have this - these outcome measures for thermoregulation. And by the way, look at Andrea Kurz's article of 1996." That's what you do; correct?

A. Yes.

Q. Okay. Let's go down -- more down page 15 --

or I'm sorry, page 10. You have, you know, six from the bottom, "Payment Issues Update." That's about the money; correct?

A. Yes.

Q. "Pay For Performance," that's about the money; correct?

A. Well I'll say -- I'll -- I'll -- I'll say it again: The discussions about pay for performance have a financial aspect to -- to them, but the explanation of the basis of the performance mea -- measures has a scientific component to it.

Q. I understand that, doctor. But people are not --

You're not giving a lecture on the benefits of normothermia and its scientific basis behind it, you're saying maintaining normothermia and it's going to affect pay for performance; correct?

A. It's -- it's both. I mean the reason we have these performance measures and created them was to drive improvements in care, and that is, as much as anything, the message of the presentations on pay for per -- pay for performance.

Q. By the way, SCIP-10 is no longer in existence; correct?

A. SCIP-10 -- SCIP-10 is no longer in

existence, but the physician quality measures that is analogous is still in existence.

Q. But SCIP-10 is no longer in existence; correct?

A. Correct.

Q. And that was dealing with thermoregulation; correct?

A. Correct.

Q. Go to page 11.

Well, you agree with me that most of page 10 deals with some issue about pay for performance or money of anesthesiologists.

A. That's correct.

Q. Okay. "A Visit to the Sausage Factory," what's that about?

A. That was a pre -- presentation made in Great -- in Great Britain about American healthcare reform and The Affordable Care Act.

Q. By the way, you agree with me that 3M -- or Arizant at the time -- was involved with the, quote, unquote, lobbying to get the SCIP measures passed; correct?

A. I don't know that.

Q. Were you involved with the SCIP measures?

A. Not -- not directly. I was involved with

the physician measures and --

I was involved with the SCIP measures only insofar as we were asked to harmonize the physician normothermia measure with the SCIP-10.

Q. Where is the physician normothermia? Where can I find that?

A. You can find it on the second and third items in Materials Considered.

Q. Oh, the Centers for Medicare & Medicaid?

A. Yes.

Q. Okay. Now you agree with me that there's nothing on page 11 that deals with maintaining normothermia, the actual research.

A. There's talk on performance measur -- measurement in anesthesiology, which, as I have previously said, would include -- include the scientific basis of the performance measures.

Q. I understand that. But you -- you're referring to other people's research in the pay for performance; correct?

A. Yes.

Q. There's nothing on page 11 that deals with any type of research that you've done on maintaining normothermia.

A. I think we've previously esta -- established

that I have not personally conducted basic clinical science research on temperature management.

Q. I just like to be a little bit thorough just in case something might trigger your brain later on to saying, "Oh, actually I did something."

So let's look at page 12. There's nothing on page 12 that deals with any type of research that you did regarding maintaining normothermia; correct?

A. Correct.

Q. Okay. And the same thing for page 13, there's nothing in there that deals with maintaining normothermia, any research that you did; correct?

A. Correct.

Q. Okay. When you were a visiting professor or named lecturer, did you do any research under that section with respect to maintaining normothermia?

A. No.

Q. Now you agree that many of your publications deal with the actual practice of anesthesia with respect to fee schedules or profitability or relative value.

A. I did not hear the question.

Q. With respect to publications, would you agree with me that most if not all of those publications deal with -- let's just say most deal

with the anesthesia practice itself, you know, Medicare fee schedule, profitability, payments?

A. Most.

Q. Okay. And sitting here today, based on pages -- on 11, there's nothing -- or on page -- I'm sorry, page 14, there's nothing on page 14 that describes any type of research that you've done on maintaining normothermia; correct?

A. Correct.

Q. And the same thing with page 15, there's nothing on page 15 that you've done that deals with maintaining normothermia; correct?

Research.

A. There's nothing that presents original clinical or basic science research by myself.

Q. Okay. And on page 16 as well, there's nothing on page 16 that deals with anything that describes any research that you've done on maintaining normothermia; correct?

A. Correct.

Q. So basically with all your --

Would it be fair to say that with respect to your knowledge of maintaining normothermia, you would defer to people such as Andrea Kurz and Dr. Sessler?

A. People such as those.

Q. Okay. Who else would you defer to?

A. Well I think, for example, Scott -- the Hopkins -- Hopkins group, Dr. Scott and coll -- and colleagues.

Q. Okay. The Hopkins group was just a single-institution study; correct?

A. Correct. I believe so.

Q. Okay. So anyone else besides Dr. Scott?

A. I can't -- I can't off -- off the top of my head say -- say -- say, but I think it is fair to say that the original research on the subject, Drs. Sessler and Kurz are prominent.

Q. I mean you would agree with me that no one knows more about the 1996 study than Andrea Kurz.

A. That's correct.

Q. Okay. The New England Journal of Medicine. You know which one I'm referring to.

A. I know which one you're referring to.

Q. As well as Dr. Sessler; correct?

A. Correct.

(Discussion off the stenographic record.)

Q. So would it be fair to say that all the opinions you're going to give today on maintaining normothermia are based on other people's work?

A. On other people's re -- research and my

clinical experience.

Q. Okay. Well let's talk about your clinical experience. Have you looked at your patients and determined the effectiveness of maintaining normothermia and done a comparison?

A. And done -- and done a compar -- comparison? No, no, I haven't. But I look at my patient's temperature constantly and on every case.

Q. I understand that. That's part of your job; correct?

A. Correct.

Q. Okay. But have you -- you --

You've only used the Bair Hugger; correct?

A. Correct.

Q. You've never used the Mistral?

A. Correct.

Q. Have you ever used the Hot Dog?

A. Correct.

Q. Have you ever used VitaHEAT?

A. No.

Q. Okay. Have you ever used Warmtouch?

A. No.

Q. Have you ever used just warm blankets?

A. In the remote past.

Q. Okay. Have you ever used reflective

blankets?

A. No, I don't believe I have.

Q. Okay. So your -- your -- your entire experience of the effectiveness of Bair Hugger is based on the fact that you used Bair Hugger for the past 25 years.

A. Correct.

Q. Okay.

A. My personal experience is based on --

Q. You -- you -- you haven't compared it yourself with any other patient warming device; correct?

A. That's correct.

Q. You know what a patient warming device is; correct?

A. Well if you want to --

A patient war -- warming device could be many -- it could be many things.

Q. I mean there's fluid warming; correct?

A. There is fluid warming.

Q. When I'm talking about patient warming, I'm talking about something that actually warms the core of the body externally.

A. Yes.

Q. Okay. And -- and there's many different

anesthesiologist has very little in common with the actual operating room --

Q. Okay.

A. -- and thus its relevance to the discussion of what's important in harming my patients is limited or nil.

Q. Okay. But --

So if there's a study that was funded by 3M discussing particle counts, you don't believe you need to look at that?

A. Particle -- particle counts mean little to me compared to surgical-site infection frequency.

Q. Okay. What research have you done on surgical-site infection?

A. I have not done original research on surgical-site infection.

Q. You're not an infectious disease expert; correct?

A. Correct.

Q. You're not an orthopedic expert; correct?

A. Correct.

Q. You're not an airflow expert; correct?

A. Correct.

Q. You're not an internal medicine expert; correct?

A. Correct.

Q. Okay. You're not -- you're not an engineer; correct?

A. Correct.

Q. Okay. You're not going to opine anything -- You're not a filtration expert; correct?

A. Correct.

Q. You're not going to offer any opinions on the operating room environment; correct?

A. That --

You'll have to be more specific about that.

Q. Okay. You agree with me --

Can we agree at least that periprosthetic joint infections are caused by bacteria?

A. Yes.

Q. Okay. Anything else that could cause a periprosthetic joint infection?

A. I -- I don't -- I don't know, but it might -- there might be such a thing as a fungal infection, but that is again not my expertise.

Q. What about a virus?

A. I have never heard of that.

Q. Okay. And you agree with me that -- that -- withdraw that.

So just so I understand, you were provided

documents by 3M or their attorneys and you didn't review them all.

A. Correct.

Q. Okay. How many documents did they provide to you?

A. Prob -- probably more than a hundred.

Q. They provided you more than a hundred documents and you didn't review --

How many did you review?

A. I -- I don't -- I don't know.

Q. Why aren't they on your list of materials considered?

A. Well I reviewed -- I reviewed those, but there's a difference be -- between looking at a doc -- looking at a document and saying this is, you know, in an -- in an area that is not going to contribute to something I'm going to have -- express an opinion about and considering it in developing my opinion.

Q. Well you're discussing particles and helium bubbles, and you just told me that you reviewed the Dr. Sessler article that you -- that you seem to going to be discussing about today.

A. That I --

Q. That you said you were going to discuss -- today you said -- strike that.

You said today you're going to discuss particles and helium and it's not representative of what's going on in the operating room; correct? The setup.

A. I -- right. I'm going to comment on the important differences between the experimental models in several -- not all -- of the -- of the studies relating to particle counts, et cetera, and my opinion that the experimental mod -- model is substantially different from a real operating room environment, which casts doubt on its relevance to the risk of infection.

Q. I understand that. My question is: What --

Do you think having people in the models, the particle or helium models, would make it better or worse for particle counts over the surgical site, if you know?

A. I -- I don't -- I don't know. But the experimental model would be more important if it -- if it had people and equipment and so forth.

Q. So you don't know, sitting here today, whether or not adding people or equipment to the operative -- operating room model would increase or decrease the amount of particles shown in these tests; correct?

A. Correct.

Q. Okay. Do you know how many skin squames are shed in a one-hour or two-hour surgery in the operating room?

A. I don't know the number.

Q. Okay. Do you know it's in the millions?

A. If you say so.

Q. You don't know?

A. I don't know.

Q. Okay. You mentioned in your report that your infection rate for your institution is .6 percent; is that correct?

A. It was at the time I last inquire -- inquired, which was earlier this year.

Q. Earlier this year?

A. Yes.

Q. Okay. And what type of infections are we referring to?

A. Total joint arthroplasty infections.

Q. Total joint?

A. Yes.

Q. Okay. And where does that information come from?

A. The Direct -- Director of the Joint Center at the hospital.

existing evidence in other settings demonstrates that, the -- risk of surgical infections, and there's no reason to believe that orthopedic surgery would be different from the surgeries that have been studied and in which a reduction in the risk of infection has been documented would be different.

Q. You -- you think a colorectal surgery where you cut the gut open and it's a dirty surgery is the same as placing an implant?

A. No, I don't think it's -- I --

I don't think the surgery is the same. Obviously, it's not.

Q. You understand that an implant deals with bacteria different than human tissue.

A. Yes.

Q. You understand that; correct?

A. Yes.

Q. I mean I know you're not an infectious disease expert, but you learned that in medical school; correct?

A. Yes.

Q. Okay. By the way, you only deal with the patient in the anesthesia or -- like pre-op, perioperatively and post-op; correct?

A. Yes.

Q. You don't deal with the patients later on when they actually get the infection; correct?

A. Correct, except for those who require additional surgery.

Q. I understand that. For an infection; correct?

A. Or dislocation or a variety of indications for reoperation.

Q. But you don't -- you don't follow your --

You don't follow the patient after they leave the post-op; correct?

A. Briefly.

Q. Okay. Okay. But whether or not they obtain a periprosthetic joint infection, there's no way for you to even know that unless they came back in and you remembered them being in the hospital before.

A. In -- in general, that's true.

Q. Okay. So with respect to -- you agree with me that there's no -- you know what -- strike that.

Do you know what evidence-based medicine is?

A. Yes.

Q. Okay. And that's where you have evidence of a certain -- evidence to support a position; correct?

A. Well, to support a practice, yes.

Q. Okay. So what evidence is there, scientific

Q. Okay. And again, if the -- if the -- if the implant is contaminated with bacteria and there's no blood flow, would you agree with me that the mechanisms in which maintaining normothermia assists in surgical-site reduction don't apply?

A. I'm not able to answer that question.

Q. You can't answer that question.

A. Correct.

MR. ASSAAD: Okay. Let's take a break.

THE REPORTER: Off the record, please.

(Recess taken.)

BY MR. ASSAAD:

Q. With respect to the International Concensus that you referred to in Exhibit No. 2, did you read the entire thing?

A. I -- I scanned it.

Q. Do you know how long it is?

A. I seem to remember about 40 pages, but I'm guessing.

Q. Forty pages?

A. Yes.

Q. Okay. Now with respect to the infection rates in your hospital --

That's the Newton-Wellesley Hospital; correct?

A. Newton-Wellesley, yes.

(Exhibit 6 was marked for identification.)

BY MR. ASSAAD:

Q. Have you heard of Hospital Compare?

A. Yes, I have.

Q. And that's done by the Medic -- by Medicare; correct?

A. Yes.

Q. Do you see where on page one of Exhibit 6 it says, "National complication rate for hip/knee replacement patients was 2.8 percent?"

A. Yes, I do.

Q. See that?

A. Yes.

Q. Okay. And then under "Hospital name" it has "NEWTON-WELLESLEY HOSPITAL?"

A. Yeah.

Q. Correct?

A. Yes.

Q. And it's check marked "No different than the national rate;" correct?

A. That is what it says, yes.

Q. That's opposite of what you put in your report; correct?

A. Uh-huh.
Q. Yes?
A. Yes.
Q. Okay. Now with respect to Andrea Kurz's deposition, what did you read in her deposition?
A. There was a discussion about the differences in how she would design the study today as compared to what she did in 1996.
Q. Okay. Did you read the entire deposition?
A. I scanned it.
Q. You scanned it?
A. Yes.
Q. Okay. Did you have a limit on the amount of time that you could spend working on this case?
A. No.
Q. Were you -- were you --
Were there any constraints on how many hours you could review materials?
A. No.
Q. Okay. You -- you understand that 3M was paying your bill; correct?
A. Was paying whose bill?
Q. Your bill.
A. Yes.
Q. Okay. And 3M is a multi-billion-dollar

A. No, that's not correct.

Q. Okay. So if your opinion is whether or not the Bair Hugger is safe for use, wouldn't internal testing be relevant to determine the safety of the Bair Hugger device?

A. Well intern -- internal testing, to the extent that it address -- addresses particles, air bubbles and other surrogates, are neither my expertise nor the basis on which I would make a clinical judgment about choosing to use the Bair Hugger or not.

Q. So if there were documents that exist that indicate that the Bair Hugger increases the bacterial load over the surgical site, that would be irrelevant to the safety of the Bair Hugger to you?

MS. LEWIS: Objection, form.

A. A, I am not qualif -- qualified to draw the connection between that finding and the risk of using the Bair -- Bair Hugger, and this is, you know, a very high -- high-volume operation and the rate of surgical infections with it is amen -- amenable to study. So my expectation, what I am looking for and what I've been looking for ever since I first heard allegations of its hazard, has been documentation that more pa -- more patients have surgical-site infections when Bair Huggers are used than when it is not used. I don't

believe such a thing exists.

Q. Okay. Do you know the difference between a surgical-site infection and a periprosthetic joint infection?

A. I'm -- I'm sorry?

Q. Do you know the difference between a superficial -- a surgical-site infection and a periprosthetic joint infection?

A. Well surgical-site infection is kind of an all-encompassing term, of which periprosthetic joint infections is one variety.

Q. Are there any allegations that you're aware of that the Bair Hugger increases the incidence of superficial surgical-site infections?

A. I -- I think the -- the action is about peri -- periprosthetic joint -- joint infections.

Q. Do you know how many bacteria or CFUs are needed to cause a periprosthetic joint infection?

A. No.

Q. Do you know if it's more or less than a superficial surgical-site infection?

A. No.

Q. Are you aware -- strike that.

You agree with me that a study could be conducted to determine whether or not the Bair Hugger

increases the incidence of periprosthetic joint infections; correct?

A. Yes, I believe that's true. But study -- study design is not my area of expertise.

Q. Okay.

A. But all right.

Q. Your area of expertise is to just criticize the literature in this case; correct?

A. My area of expertise is making clinical decisions about caring for my patients.

Q. And your clinical decisions are based on literature that you have read; correct?

A. Yes.

Q. Okay.

A. Well let -- let me --

Q. Yes.

A. Let me, if I may, continue.

Q. Sure.

A. My clinical decision-making is based on -- not only on literature I have read but, when you look at the list of materials, the systematic analyses that groups like ECRI and NICE -- and NICE and others have done, and those groups, because they are thor -- thorough, impartial and have advanced methodological skills, the conclusions they draw from their analyses

Do you know what a 510(k) clearance is?

A. I -- I -- I heard the term.

Q. Okay. You understand that, with respect to the safety of medical devices or even drugs, that the government relies on information provided by the manufacturer?

A. If you say so. I have no experience in the --

Q. Okay.

A. -- 510(k) process.

Q. Okay. And you're not going to be providing any opinions on warnings since you don't understand the FDA process; correct?

A. Well I'm not going to give an opinion about what the FDA requires or not -- doesn't require. I can give -- give an opinion about the warnings that I -- I see as a user of the -- of the device if you have questions about that.

Q. Well what is your expertise in medical device warnings, if any?

I'll withdraw the question. Have you yourself --

You've never created a medical device; correct?

A. Correct. Correct.

Q. You've never been advised on --

You've never been consulted on what warnings should be on a medical device; correct?

A. Correct.

Q. You've never actually written warnings in your entire life; correct?

A. Correct.

Q. Okay. You -- you -- you don't know --

You've never had any discussions with respect with orthopedic surgeons and whether or not they look unfavorably with respect to particles; correct?

A. Correct.

Q. You're not an expert in airborne contamination; correct?

A. Correct.

Q. You're not an expert in infectious disease; correct?

A. Correct.

Q. You're not an expert in -- in -- in forced-air warming; correct?

The device itself.

A. Correct.

Q. Okay. Do you even know how much heat comes out of the Bair Hugger?

A. We talked a little bit earl -- earlier, again -- again I need to look at the statistics in Frisch, but there was a diff -- a difference in the frequency of infections in those patients.

Q. Well you're --

You hold yourself out as an expert in maintaining normothermia; correct?

A. I hold myself out as a -- yeah, somebody who has made that a clinical goal.

Q. That's not my question of making a clinical goal.

A. Yeah.

Q. Okay? I -- I make many goals in my life but I'm not an expert in. Okay?

My question is: Do you consider yourself an expert in the risks and benefits of maintaining normothermia?

A. Yes.

Q. Okay. So you should know the studies that you're going to rely upon because you yourself have done no research on the issue; correct?

A. I have, as I said previously, heavily re -- relied on systematic analyses of groups expert in summarizing the available findings, such as ECRI, NICE, and the physician consortium and the others I've

identified.

Q. Okay. And they're relying on Kurz, Melling and --

A. Well they're -- they're -- they're look -- they're looking at McGovern and Legg and everybody who has published on this. Right?

Q. Well here -- here's the unfortunate thing, sir. Okay? You've been designated an expert in this case as to maintaining normothermia; correct?

A. I -- that's why --

Q. Okay.

A. That's why I'm here.

Q. So you can't rely on other groups that have done reviews --

A. No, I -- I disagree with that. I certainly can.

Q. Okay. So you're going to rely on -- on -- on other people, so I could just read what they say and that's what you're going to say.

A. To a -- to a degree.

Q. Okay.

A. They have very -- they have --

They are very persuasive in my decision-making.

Q. Okay. So sitting here today, besides Kurz,

maintaining normothermia reduces the incidence of surgical-site infections?

A. It reduces the in -- incidence of infectious complications of all -- of any kind.

Q. That wasn't my question, sir.

A. Correct. No difference in surgical -- surgical-site infections to the extent that the study methodology would distinguish between those infections and the others.

Q. Well they actually did distinguish it; didn't they?

A. Well they said they did.

Q. Have you looked at the data?

A. I -- I looked at the source of the data, which is administrative data, which depends on -- on coding for the purpose of -- of billing.

(Exhibit 7 was marked for identification.)

MR. ASSAAD: No. I'm sorry. I gave you the Sun article. We'll get to this in a second. Sorry.

BY MR. ASSAAD:

Q. Are you familiar with this article, sir, the Sun article?

A. No, I don't think I am.

Q. With Dr. Sessler and Andrea Kurz?

A. No, I don't think I am.
Q. Okay. Why don't you look at the conclusions, tell me if you agree with this.
A. Which one?
Q. "Even in actively warmed patients, hypothermia is routine during the first hour of anesthesia." Do you agree with that statement?
A. Yes, temperatures drop in the first hour of anesthesia.
Q. Okay.

(Exhibit 8 was marked for identification.)

BY MR. ASSAAD:
Q. Exhibit 8 is titled "Compliance with Surgical Care Improvement Project for Body Temperature Management (SCIP-10) Is Associated with Improved Clinical Outcomes" by Andrew V. Scott et al. Is this the article you're referring to?
A. Yes, it is.
Q. Okay. Let's turn to page five. Under "Wound infection" --

That's a surgical-site infection, correct, on -- on Table 4?
A. Yes. Yeah.
Q. Do you agree with me that SCIP non-

compliant has a lower infection rate than SCIP compliant?

A. Not in a significant way -- way.

Q. That wasn't my question.

A. Yes.

Q. It's lower; correct?

A. The raw -- the raw numbers are lower.

Q. Okay. It's not statistically significant --

A. So I would characterize it as no difference.

Q. Okay. And this is 2015; correct?

A. Correct.

Q. Published in Anesthesiology; correct?

A. Correct.

Q. And you subscribe to Anesthesiology; correct?

A. Yes.

Q. And you believe that's an authoritative journal; correct?

A. It's a reputable journal.

Q. You -- you think it's authoritative.

A. I believe it has -- has a robust editorial process.

Q. And you've cited to this article in your Materials Considered; correct?

A. Yes, I have.

Q. So you believe it's authoritative.

A. I believe -- I -- it is --

It is there because it influenced my opinion on the safety of the Bair Hugger.

Q. Okay. Well it doesn't really talk about the safety of the Bair Hugger, it talks about the efficacy of the Bair Hugger.

A. No. I think the frequency of the complications stud -- studied goes directly to the question of safety.

Q. Is there anything in Scott that discusses whether or not the Bair Hugger contaminates the sterile field through either being contaminated itself or by disrupting laminar flow?

A. No. That's the beauty of the Scott paper, is that it talks about clinical outcomes and what matters to patients.

Q. Well the beauty is, then, that there's no difference in wound infections between maintaining normothermia and not maintaining normothermia; correct?

A. Normothermia in this study was maintained -- maintained with the use of the Bair Hugger. There being no difference in wound infections and a dramatic difference in all infections, in addition to the other

complications, tells me that it is a safe -- a safe device and is good practice to -- to use.

Q. What -- what percentage of patients that have peri -- total knee or total hip actually have -- get sepsis?

A. I don't know.

Q. Okay. What -- what percentage of patients that have total hip or total knee actually have a drug-resistant infection?

A. I did not -- I don't --

I don't know.

Q. Okay. What percentage of patients have some sort of an ischemic cardiac -- cardiovascular event, of total hip or total knee patients, arthroplasty patients?

A. I don't know.

Q. Okay.

A. I don't know that they are different -- different from this diverse group of surgical patients.

Q. You agree with me that this article does not talk about whether or not the Bair Hugger contaminates the sterile field by its use.

MS. LEWIS: Objection, form.

A. It dis -- it discusses the out -- outcomes

that would make that finding relevant but doesn't discuss the contamination of the surgical wound -- wound directly, only the clinical marker of that event.

Q. Well it --

I mean you believe maintaining normothermia reduces the risks of surgical-site infection; don't you?

A. Yes.

Q. You do. But this study says the opposite with respect to wound infections; correct?

A. No, it says there's no difference.

Q. Well SCIP non-compliant means either, one, they --

Well SCIP non-compliant means they didn't use any type of maintain -- forced-air warming or patient warming.

A. Or didn't achieve the target temperature.

Q. No. You could still be SCIP compliant as long as you --

As long as you're using a forced-air warming --

A. Correct.

Q. -- device you're SCIP compliant; correct?

A. Right, but --

And if you don't use it and meet the target temperature, you're also SCIP compliant.

Q. Yes. So the ones that they did not --

SCIP non-compliant means that you weren't at the target temperature and you did not use a patient warming device; correct?

A. Correct.

Q. Okay. So we could agree, for the SCIP non-compliant, no patient warming device was used.

A. Or a patient warming device was used -- was used --

No. I'm sorry. Correct.

Q. I'm correct.

A. Okay.

Q. Right?

A. You are.

Q. Okay. So we have here on page five 1,240 patients that no patient warming device was used on; correct? Correct?

A. Correct.

Q. Okay. And then you have the SCIP compliant, which has 44,000 patients that warming was used; correct?

A. Correct.

Q. And it was forced-air warming in this case;

correct?

A. Yes.

Q. Now since you believe that forced-air warming or patient warming reduces the incidence of surgical-site infection, why is there no difference for wound infections?

If you know.

A. Well I don't -- I don't know, I don't know, but the -- the size of the two -- two groups may produce a statistical effect that produces this. But as I said, this informs my opinion, because if forced-air warming were dangerous, I would expect to see the SCIP compliant group have a substantially higher rate of wound infection and other -- and other infectious complications than the group in which it wasn't used, --

Q. Did you ever think --

A. -- and that is not the case.

Q. Did you ever think of this possibility, sir, that maintaining normothermia reduces the incidence of wound infection but it's been offset because of the risk of the Bair Hugger and that's why you get equal numbers? Isn't that -- isn't that a possibility?

A. Well if this were the on -- were the only study in existence addressing this and the others

didn't -- didn't exist, that would -- might be an attractive theory to explain the result.

Q. And you need further research; correct?

A. Well I have several -- several other studies that show a reduction in infections.

Q. Okay. But with respect to Sun, that -- if that -- that's a possibility --

A. We're talking about Scott; right?

Q. Or Scott. That's a study that you would maybe require further research to determine whether or not the Bair Hugger is increasing the infection rate but at the same time reducing the wound infection rate so you get a non-statistically significant between use and non-use. It's a possibility; correct?

A. I -- I suppose it's a possibility.

Q. Okay. So what study do you want to talk about next, Kurz or Melling?

A. You're -- you're asking the questions.

Q. Okay. Let's talk about Melling. Is Melling perioperative warming?

A. Melling is perioperative warming.

Q. Is that what you believe?

A. It's perioperative warming.

Q. Are you sure about that?

A. Yeah.

Q. Okay. And you believe Melling supports the safety of the Bair Hugger perioperatively.

A. Well the Bair -- in this --

In this case, this is about hypother -- hypothermia and the frequency of infections in clean -- in clean surgery. There were two modalities used, neither in the operating room, but the patient's temper -- temperatures or the surgical-field temperature -- temperatures in some of the cases was managed with local warming or body -- body warming perioperatively.

Q. You understand that Melling is -- is preoperative warming.

A. Yes.

Q. Okay. When --

A. And when you said -- when you said "perioperative warming," in my mind that includes preoperative.

Q. Okay.

A. But the point here is the effect of warming.

Q. You agree with me that prewarming lasts for about three hours based on the science.

A. Yeah. I don't -- I don't know about that, but these patients --

Q. Okay.

A. The warmed patients were not surprisingly warmer.

Q. Melling wasn't --

Bair Hugger wasn't used from incision to incision.

A. Correct.

Q. Okay. So Melling was not used intraoperatively; correct?

A. Correct.

Q. Okay. So Melling wouldn't indicate whether or not the use of Bair Hugger would contaminate the sterile field because the Bair Hugger wasn't used intraoperatively; correct?

A. Correct. Melling speak -- speaks to the importance of normothermia in reducing the risk of surgical infection.

Q. The effect of prewarming on normothermia.

A. Norm --

Q. Okay.

A. Normothermia.

Q. Okay. Let's talk about Kurz. Do you recall reading any -- anything in the deposition of Andrea Kurz where she stated that, with -- let me get the exact words --

MS. LEWIS: Are you going to have a copy for

Dr. Hannenberg?

MR. ASSAAD: No.

MS. LEWIS: Okay. I just want the record to so reflect.

MR. ASSAAD: Next time maybe if you instruct your witnesses to come with information so they can answer questions --

MS. LEWIS: Since they don't know what question you're going to ask, --

MR. ASSAAD: That's why they should bring everything.

MS. LEWIS: -- they're supposed to guess?

MR. ASSAAD: I mean you go to trial with all the files; don't you? I don't know if you go to trial, but if you do, you should bring all the files.

Q. So do you recall when Dr. Kurz indicated that Kurz would not meet current research guidelines and -- and scientific reliability in -- in -- in today's world?

MS. LEWIS: Dr. Hannenberg, if you remember, that's fine; if you don't, if you want to see the document --

THE WITNESS: Seeing the document would be helpful.

(Exhibit 9 was marked for

AFTERNOON SESSION

BY MR. ASSAAD:

Q. Are you ready to continue, doctor?

A. Yes, I am.

Q. Before I get to the Kurz deposition, we were talking about some of the articles that support your opinion that maintaining normothermia reduces the incidence of infection. You -- you haven't been provided any internal documents or minutes regarding conversations with Andrea Kurz or Dr. Sessler within 3M; have you?

A. I don't believe so.

Q. Okay.

(Exhibit 10 was marked for identification.)

BY MR. ASSAAD:

Q. Exhibit 10 is a document provided to the plaintiffs from defendants talking about the Global Patient Warming Advisory meeting on October 18th, 2012. Do you see that as the heading?

A. Yes, I do.

Q. And you see that the board members are Dan Sessler, Pedro Barbieri, Andrea Kurz, Claude LaFlamme and Berthold Bein. Do you see that?

A. Yes, I do.

infection was not defined, core temperature not recorded(!)"

Were you aware of the significant and serious flaws of the Melling paper?

A. I think the Melling paper is also infor -- informative despite -- despite these comments.

Q. Okay. But you would agree with me, especially with the Kurz paper, that Andrea Kurz knows more about her paper and the limitations than you do.

A. She does.

Q. Okay. Let's go to the deposition of Andrea Kurz. I'd like you to turn to page 179. If you look at page 179 of Andrea Kurz's deposition, which is marked as Exhibit No. 9, line 16:

"Question: In today's scientific standards, there is no reliable evidence that supports that maintaining normothermia reduces the incidence of infection.

"Answer: That is correct."

Do you agree with that statement and answer?

A. No.

Q. Okay. So you disagree with Andrea Kurz.

A. Yes.

Q. Okay.

MS. LEWIS: I'm sorry, tell me what page

number we are again.

MR. ASSAAD: 179.

MS. LEWIS: Okay. Thank you.

Q. So Andrea Kurz, who has done more research than most people in the world on maintaining normothermia and its effects, you, as a person who's never done research on maintaining normothermia, disagree with Dr. Kurz.

A. Yes.

Q. Okay.

A. I disagree with that -- with that statement. I'm sure there are many things Dr. Kurz has said that I agree with, but with respect to that statement, yes, I disagree.

Q. You disagree with that statement. Okay.

A. I disagree with that statement.

Q. And what's your basis to disagree with that statement?

A. Because her research is not the -- the only evidence that addresses this -- this question, and we've already talked about oth -- others and other more recent research.

Q. Well, with respect to surgical-site infections, what valid scientific evidence is there that indicates that maintaining normothermia reduces

the incidence of surgical-site infections?

A. Kurz, Melling.

Q. Okay. Anything else?

A. The --

No, I would say I would point to those.

Q. Okay. So you disagree with Dr. Kurz's opinions on her own study that you're citing to support maintaining normothermia reduces the incidence of infections.

A. Well I'm not --

So this statement of hers is conditioned by the phrase "In today's scientific standards," and I don't know what she means by -- by that.

Q. Well if you read the deposition --

A. Or that's your -- that's your ques -- that's your question. I'm not sure what -- what you mean by that.

Q. And you've had a copy of this deposition; right?

A. I had a copy of this deposition.

Q. Okay. And you had a chance to read it; correct?

A. I did.

Q. Okay. And you were never provided a -- a copy of Exhibit No. 10; were you?

A. Which is Exhibit No. 10?
Q. The minutes.
A. I don't believe I was, --
Q. Okay.
A. -- no.
Q. Were you ever informed that Dr. Sessler indicated in 2016 saying that knowing what he knows now, that he would have never published the 1996 Sessler paper with Dr. Kurz?
A. I'm not aware of that statement.
Q. Would that affect your opinion with respect to the quality of the 1996 study?
A. I -- I -- I don't know why he said -- why he would say that.
Q. So you're not aware that he's made that statement in the past; correct?
A. I am not aware of that.
Q. And if he did make that statement, would it change your opinion?
A. Again, it would depend why he was saying it, what he was thinking.
(Exhibit 11 was marked for identification.)
BY MR. ASSAAD:
Q. What's been marked as Exhibit 11 is an

outcomes leading to patient morbidity and mortality beyond surgical wound infections, and the inescapable conclusion from looking at Scott is that -- is that managing patient temperature with forced-air warming benefits the patient.

Q. But you can't say that with re -- with respect to total hip and total knee arthroplasties because you don't know, the surgeries that occurred, which ones applied to orthopedic surgeries, correct, with Scott?

A. Scott does not iden -- identify which orthopedic procedures.

Q. But what we can say for sure in Scott is that with respect to wound infections in orthopedic procedures, there is no difference between SCIP compliant and SCIP non-compliant.

A. I don't think Scott broke out wound infections for separate analy -- for separate analysis.

Q. Okay. Are you familiar with the Clarissa Tjoakarfa study --

A. Does not sound familiar to me.

Q. -- entitled "Reflective Blankets Are as Effective as Forced Air Warmers in Maintaining Patient Normothermia During Hip and Knee Arthroplasty

Surgery?"

A. No, I'm not familiar with that. No.

Q. Okay. Do you know why they are not --

Do you have an opinion whether or not reflective blankets are as efficacious as forced-air warmers in total hip and total knee arthroplasty surgeries?

A. Do I have an opinion?

Q. Yes.

A. Yes, I have an opinion about that.

Q. What's your opinion?

A. They are not as effective as active warming.

Q. What study have you performed to determine that?

A. You asked for my opinion, not for the result of a study.

Q. Well I'm hoping --

I don't want you to guess. Your opinion is based on some sort of fact or science. Do you have any fact or science to support your opinion that forced-air warming is more effective than reflective blankets?

A. No, I can't -- I can't --

Q. Okay.

A. -- point to that study.

Q. You're familiar with the studies comparing forced-air warming to the Hot Dog device; are you -- are you not?

A. I -- I have not -- I -- I have not studied -- studied them. My interest in this has not been so much about the comparative efficacy but the safety of the Bair Hugger, --

Q. Okay.

A. -- and so those are somewhat off point.

Q. Okay. Just so I understand, your opinion is that since there's no article that you agree with or you think is credible that the Bair Hugger is unsafe, that it must be safe.

A. That is in -- in part true, but it is also -- my opinion is also based on the fact that there is evidence that the risk of infections declines with the use of the Bair -- Bair Hugger, and that un -- unless I saw a clinical outcome study showing me -- showing me that the Bair Hugger was unsafe in that respect, I would continue to support its use and advocate for its safety.

Q. Can you --

And -- and try to get out for a second the -- the fact that you honestly believe that maintaining normothermia reduces the risk of

non-responsive.

Q. Listen to my question. Are you aware of any study that indicates that the Bair Hugger does not increase the bacterial load over the surgical site?

A. I -- I am not aware of it.

Q. Okay. Do you know what the Mistral warmer is?

A. I've heard -- I've heard of it.

Q. You know it's a forced-air warming device?

A. Yes, I know that.

Q. You know it's made by Stryker?

A. I didn't know that.

Q. Okay. Are you aware that Mistral, which is a forced-air warming device, warns the doctors regarding potential airborne contamination by its product?

MS. LEWIS: Objection, form.

MR. ASSAAD: Basis.

MS. LEWIS: It mischaracterizes the evidence, it's not a warning, and y'all have talked about that in other depositions.

MR. ASSAAD: Not a warning?

MS. LEWIS: No.

MR. ASSAAD: Okay.

A. I'm not aware of the non-warning.

Q. It is a warning. Your counsel is wrong. So --

A. I'm not --

I -- I -- I have a passing familiarity --

Q. Okay.

A. -- and recognition of the brand name and nothing -- know nothing more about Mistral.

Q. Are you aware that the older models of Bair Hugger --

Have you ever seen a model 200 series Bair Hugger?

A. I doubt -- I doubt it. I think the models I use are 500 series plus.

Q. And 700 series?

A. That I don't know about.

Q. Have you looked at the warning labels on the 200 series?

A. No, I don't think I've seen the 200.

Q. Has counsel showed you those labels -- I'm sorry.

Has counsel showed you those labels?

A. No, I don't believe so.

Q. Okay. Do you understand there was no verification testing on the Bair Hugger?

A. What does "verification testing" mean?

A. It's mixing with the very substantially cool air in the room.

Q. You think it could change the temperature in the room by a few degrees?

A. No.

Q. Okay.

(Exhibit 14 was marked for identification.)

BY MR. ASSAAD:

Q. Exhibit 14 is a peer-reviewed article titled "Resistive-Polymer Versus Forced-Air Warming: Comparable Efficacy in Orthopedic Patients," and it's authored by Brandt, among others, including Oguz, Kurz and Kimberger.

Have you seen this article before?

A. No, I don't have.

Q. Okay. Under the conclusion it says, "Resistive-polymer warming performs as efficiently as forced-air warming in patients undergoing orthopedic surgery." Do you have any disa -- do you have any disagreement with that conclusion?

A. I have no basis to agree or disagree.

Q. Because whether or not you think maintaining normothermia is real science or junk science, it doesn't matter which way you warm, correct, as long as

you warm the patient?

A. As long as you warm the patient safe -- safely and effectively.

Q. I'd like you to turn to page 836, "Environment" -- I want you to look under Table 1, "Environmental temperature at 1 meter distance to warming device (after 30 minutes)," and do you see where it says 24.4 degrees plus or minus 5.2 degrees for Bair Hugger and 22.6 degrees plus or minus 1.9 degrees for Hot Dog?

A. Yeah.

Q. Huh?

A. Yes, I do.

Q. Okay. And you see that the OR temperature started at 19.5 degrees --

A. Uh-huh. Yeah.

Q. -- and it ended at 19.4? Do you see that?

A. Yeah.

Q. And around the warming device, at a one-meter distance around it, the temperature raised five degrees. Do you see that?

A. I -- I see that.

Q. And up -- and at some point up -- up over 10 degrees Celsius for the Bair Hugger based on the standard deviation.

Were you aware of this article, sir?

A. I said no.

Q. Has counsel -- has -- has counsel --

Would you be surprised if you were provided this article in the hundreds of articles that you received from --

A. It's poss -- it's possible it's --

Q. Okay.

A. -- it's -- it's in there.

Q. You just didn't review it before; correct?

A. As I said and you said your -- yourself, the point -- the point here is that we want to achieve normothermia safely, so my focus in reviewing the articles has been on the safety more than the efficacy.

Q. Would it be --

A. The other point -- the other point I make about this is that if -- if the Bair Hugger serves to warm the up -- rise -- raise the temperature around the patient, is that -- is that bad?

Q. Do you know if it's bad or not?

A. I don't think it's bad. I think we try very hard to warm the area around the patient. I think operating rooms are -- are too -- too cold.

Q. Do you know what the effect of heat is

around the operating room table on the sterility of the surgical site?

"Yes" or "no."

A. No.

Q. Okay. Move on then.

Do you think the data with respect to cardiac morbidity and thermoregulation is strong or weak?

A. It is strong.

Q. Have you done any research on it?

A. No, I haven't.

Q. Who has done research on it that you're aware of?

A. The original study we cited in the performance measure was -- was Frank, but I think that that was one of the endpoints also studied in -- in Scott. Wherever Scott is. Yeah.

Q. It's what?

A. It says Scott showed a reduction by 50 percent in the frequency of ischemic cardiovascular events, but the Frank, which is -- is also an older paper, also studied vascular patients and showed a lower frequency of morbid cardiovascular events in warmed patients.

Q. But you don't know what percentage of total

THE REPORTER: Off the record, please.

(Recess taken.)

BY MR. ASSAAD:

Q. Ready to continue?

A. Yes, sir.

Q. So doctor, we talked about the Kurz study, the Melling study and the Scott study; correct?

A. We have.

Q. And the one study that we haven't talked about that you believe is authoritative is Frisch; correct?

A. I believe Frisch has influenced my opinion about the safety of the Bair Hugger --

Q. Okay.

A. -- and the -- and the efficacy of normothermia.

Q. All right.

(Exhibit 15 was marked for identification.)

BY MR. ASSAAD:

Q. Is Exhibit 15 the Frisch article you're referring to?

A. No, it's not.

Q. Okay. So you're looking at the one on hip fractures, not on hip and knee arthroplasty.

A. Correct.

Q. Would you agree with me that the one dealing with hip and knee arthoplasty are more relevant to this case than hip fractures?

A. Ever so slightly.

Q. What do you mean "ever so slightly?"

A. Because the nature of hip-fra -- hip-fracture surgery is very similar to hip arthro -- arthroplasty, so I think, even more so than the other studies, we're talking about the conclusions one would draw from that have special bearing on at least hip arthroplasty if not knee arthroplasty also.

Q. Well do hip fractures all have implants?

A. They have -- all have some kind of hard -- hardware.

Q. Okay.

A. Whether --

Some of them are repaired with a hemiarthroplasty, which, as its name implies, is very similar to a total hip arthroplasty.

Q. Okay. But you --

I mean this is the same Frisch though; correct?

A. I believe it is.

Q. Okay. Had you seen this article before?

A. No, I don't believe I have.
Q. You have?
A. No, I don't believe so.
Q. You haven't. Okay.
I'd like you to go to page 60 of the article. And this was published in 2016. Are you aware of that?
A. It says 2017, but if you say it was published in 2016 --
Q. Oh, I'm sorry, you're right, 2017. It was -- it was submitted in 2016.
A. Okay.
Q. Do you see Table 3 where it indicates "Univariate Analysis of Complications Associated With Hypothermia?"
A. Yes, I do.
Q. And you see it says at the top TJA, and then halfway down -- a little more than halfway has TKA, do you see that?
A. Yes.
Q. And then if you go to the second -- other column it has THA on the right-hand side.
A. Yes.
Q. Okay. And also has p-values.
A. Yeah. So I infer from that that TJA is the

there; correct?

A. Yes.

Q. Okay. And this is dealing with the same type of surgeries that are involved in this multi-district litigation.

A. Yes, it is.

Q. So based on this article and this raw data -- this data, you would agree with me that whether a patient is normothermic or hypothermic doesn't have an effect on total knee and total hip arthroplasties for an MI, a stroke, a DVT -- DVT, a PE, a DSSI, an SSI, an NSSI and an LOS, which is length of surgery.

A. I would agree that this study fails to demonstrate that difference.

Q. Or demonstrates that there is no difference.

A. Correct.

Q. Okay. And this is 2017; correct?

A. Correct.

Q. You were not provided this article by the defendant; were you?

A. I don't --

It does not look familiar to me.

Q. Okay. And this is one year --

This is an article that's dated one year

after the Frisch article that you cited; correct?

A. The Frisch article I cited was 2016.

Q. Okay. And it's the same author.

A. I believe it is.

Q. Okay.

A. N.B. Frisch, yeah.

Q. I'd like you to go to Exhibit 7, which is the Sun study.

A. Sun, yes.

Q. This was Anesthesiology, a peer-reviewed ar -- journal. Are you familiar with Anesthesiology?

A. Yes, I am.

Q. Do you subscribe to it?

A. Yes, I do.

Q. Do you recall ever seeing this article?

A. No.

Q. Do you keep up to date with the literature in intraoperative core temperature management?

A. No more so than other clinical topics.

Q. No --

A. No more -- no more so to -- today than other clinical topics.

Q. Well do you focus on like maintaining normothermia and the literature out there on it?

A. Yes.

Q. Okay.

A. And it said nine trials, each of -- each of which had an array of culture -- culture media. And again, my recollection is that in the nine trials, none of the arrays of culture media grew any bacteria.

MR. ASSAAD: Move to strike as non-responsive to a non-existent question.

Q. You next talk about the body heat emanating from the surgical staff. Do you know how many BTUs per hour the Bair Hugger produces?

A. No.

Q. Do you know how many BTU -- BTUs per hour a -- a person produces?

A. No, I don't.

Q. Okay. Do you know --

I mean you're not an expert in heat transfer; correct?

A. Correct.

Q. You're not an expert in fluid dynamics; correct?

A. Correct.

Q. So you have no opinion with respect to how the Bair Hugger blanket may affect the OR environment by the heat it produces or the airflow it produces.

A. Correct.

The commentary here is questioning the studies that claim to describe how the Bair Hugger influences those factors.

Q. Excuse me. I didn't understand you.

A. The commentary in this letter are meant to address the shortcomings in the studies that purport to address the disruption in laminar flow and related -- related factors; that is, as we've discussed previous -- previously, the -- the experimental mod -- model either having no per -- personnel, mannequins, no instruments, no Bo -- no Bovies, et cetera, so in looking at -- at those, my conclusion was they -- for me, not being a particle or airflow expert -- they still lacked face validity on that basis.

Q. Well hypothetically speaking, if by adding individuals would make the effect of the Bair Hugger worse, would that affect your opinions regarding those studies?

A. Regarding these studies. But what I would say is that the studies of particle counts and air -- airflow patt -- patterns, their relevance to the risk of infection is un -- is -- is unproven, so that even if the particle counts --

Q. I'm not talking about infection, I'm talking

about particle counts and bubbles.

A. Well --

Q. Okay? If --

A. And I'm -- I'm going to -- I'm going to say -- say that from my point -- point of view, particle counts and bubbles are poor proxies or surrogates.

Q. And what's your basis?

A. Because I have not seen any evidence connecting them with the risk of infection.

Q. Have you not looked at the Darouiche study?

A. Show me the Darouiche study.

Q. Have you looked at it? "Yes" or "no."

A. That doesn't sound familiar.

Q. Okay. Defense are very -- all aware of the Darouiche study and the Stocks study. Have they not shown that to you?

A. Stocks --

MS. LEWIS: Objection to the form of the question.

A. Stocks sounds familiar. Rouiche -- Rouiche -- Rouiche does not.

Q. Do you know who Rabih -- do you know who Rabih Darouiche is?

A. No.

Q. So you're not aware of his study that -- that correlated bacterial load over the surgical site with periprosthetic joint infections.

A. No.

Q. And in fact not --

He even went further and said the bacterial load had an effect on periprosthetic joint infections but not superficial wound infections. Are you aware of that study?

MS. LEWIS: Objection to the form.

A. Are you talking about the same study?

Q. Yeah.

A. Same study? No, I'm still not aware of.

Q. Would that affect your opinions if those statements are true?

A. The --

MS. LEWIS: Objection to the form of the question.

A. Yeah. Repeat the question.

Q. Darouiche --

In the Darouiche study, he correlated bacterial load with periprosthetic joint infections and also showed there was no relation between bacterial load over the surgical site and superficial wound infection. If -- if that study is accurate,

would that change your opinion with respect to bacterial load causing periprosthetic joint infection?

MS. LEWIS: Object to the form.

A. It -- it might, but I would not make any conclusion about that without the opportunity to review it in -- in detail --

Q. Okay.

A. -- and presuming that the details of the study -- study were i -- i -- items with which I could intelligently, based on my background and experience, assess.

Q. Let me ask you this, doctor: Hypothetically speaking, if the Bair Hugger increased particles over the surgical site, and assuming that the increased particles over the sur -- over the surgical site indicated increased bacterial load over the surgical site, and there was also a study that indicated increased bacterial load over the surgical site increases the risk of total hip and total arthroplasty periprosthetic joint infections, would that change your opinion with respect to whether or not the Bair Hugger significantly increases the risk of periprosthetic joint infections in total hip or total knee arthroplasty --

MS. LEWIS: Objection --

Q. -- if all the statements are true?

MS. LEWIS: Objection to form.

A. Perhaps, but not to the extent that a clinical outcome study, Bair Hugger/no Bair -- Bair Hugger, would -- would have.

Q. Who do you think would fund a study with respect to the clinical outcomes on total hip and total knee arthroplasty periprosthetic joint infections with the use of the Bair Hugger or the use of a different warming device?

A. I'm not able to speculate on who might fund that.

Q. Do you know how much that study would cost?

A. I don't know.

Q. Would you be surprised it would be millions of dollars?

A. Would I be -- would I be surprised? No, I wouldn't be surprised.

Q. I mean just say assuming that the periprosthetic joint infection rate for total hip and total knee is two percent, do you know how many patients you would need to conduct a study to show a difference in an infection rate that's only two percent?

A. No, I don't know the number.

Q. Okay. More than 10; right?
A. Yeah. Presumably, yes.
Q. Probably more than a thousand.
A. I -- I -- I don't know.
Q. With respect to McGovern, you criticize McGovern because of the change in infection prevention practices during the study period; correct?
A. Among other things, yes.
Q. Well that's what you put here. Oh, motionless. But with regard --
With respect to the clinical data, it's the change in infection prevention practices; correct?
A. And the anticoagulation practices.
Q. Well that's not in here; is it?
A. No, but it's true.
Q. Well I'm looking at your report. It's not in your report; correct?
A. Yes, that's true.
Q. Okay. So let's just talk about the infection prevention practices. Are you talking about the prophylactic antibiotics?
A. Yes.
Q. Do you know whether or not the change in the pro -- that the prophylactic antibiotics -- strike that.

Are you aware of any study that compares the two anti -- different antibiotics that were used to determine whether or not any one of them had a -- a better or worse effect on periprosthetic joint infections?

A. I -- I -- I don't know.

Q. Okay. If there was a study that indicated that the prophylactic antibiotics were -- they -- they were not inferior to each other, would that affect your opinion of whether or not the change in antibiotics had an effect on the results?

A. I -- I -- I think the results of this -- this study should control -- controlled for that.

Q. Well why don't you answer my question.

A. If there were effectively no change in the anti -- antibiotic --

Q. That wasn't my question, sir. Why don't you listen to my question. We'll -- we could get out of here really soon. If there is --

If there was a study that indicated that the two antibiotic -- the two different antibiotic regimens used in the McGovern study were non-inferior to each other, means there was no difference, would that affect your opinion of whether or not the change in the prophylactic antibiotics used had an effect on

the McGovern results?

MS. LEWIS: Object to the form.

A. I would be -- I would be less -- less concerned --

Q. Okay.

A. -- but not unconcerned.

Q. Okay. You say that more than 5,000 public and private institutions rely on ECRI. Is that correct?

A. Yes.

Q. What's your basis?

A. ECRI.

Q. So you rely on ECRI to tell you who relies on ECRI?

A. ECRI -- yeah. I think that came from ECRI's annual -- annual report.

Q. Well there's a difference of public and private institutions relying on ECRI or them -- or people subscribing to the ECRI website. Do you understand the difference?

A. Okay. Okay.

Q. I mean you subscribe to the Anesthesiology Journal; correct?

A. Yes.

Q. You don't rely on every article that's

published in the Anesthesiology Journal; correct?

A. But to a degree I rely on it; otherwise, why would I subscribe to it?

Q. Because there might be some good parts, there might be some bad parts; correct?

A. Correct.

Q. I mean there's some articles that I assume an independent doctor would read and be like I just disagree with -- with the research or disagree with the conclusion; correct?

A. Yes.

Q. Even though you subscribe to Anesthesiology; correct?

A. Yes.

Q. So you really can't sit here and say that more than 5,000 public and private institutions rely on ECRI for evidence, reports and assessments of healthcare technology, but what you can say is there's probably 5,000 people that subscribe to it. Fair?

A. Yeah. I'm not sure that it's people as much as institutions.

Q. Okay. You don't know whether or not the institutions are relying on the data that ECRI provides; correct?

A. I don't -- I don't know the extent to which

they do so.

Q. That would be pure speculation; correct?

A. Correct.

Q. Okay. Now you'll agree, with respect to the heater-cooler devices, that the bacteria was aerosolized on water vapor and traveled to the patients; correct?

A. That is -- that is what was reported.

Q. Okay. And you have no reason to disagree with that; correct?

A. I have no reason to disagree.

Q. It wasn't by direct contamination but by indirect contamination.

A. I'm not sure what you mean by "direct contamination" or "indirect contamination."

Q. You don't know the difference?

A. I don't know what you mean.

Q. Okay. When you say it's been aero -- aerosolized, it traveled through the air; correct?

A. In -- in -- in liquid.

Q. Okay.

A. In water.

Q. In water vapor.

A. In water vapor.

Q. Okay. Do you know how small a water vapor

is?

A. I don't know.

Q. Do you know whether water vapor is equivalent in travel -- in the way it travels in the air to neutrally buoyant bubbles?

A. I don't know.

Q. Do you know whether or not it is similar to the way it travels with squames?

A. I don't know.

Q. Okay. But we do know that water vapor could travel from where the heater-cooler is and -- and blown by the fan of the heater-cooler to the surgical site; correct?

A. That is what the alert implied.

Q. Okay. And you're aware that the heater-cooler unit is much further away from the sterile field than the Bair Hugger is.

A. I don't know that.

Q. Okay. You've never used a heater-cooler unit?

A. Well I've been many -- many years ago in a cardiac opera -- operating room, but it depends where the pump -- where the pump and the heater-cooler sit.

Q. And you're not disputing that an implant can be contaminated by airborne contamination; are you?

A. I think it is -- I think it is possible. I think contamination of sur -- of surgical wounds is principally from the skin and subcutaneous flora of the patient.

Q. Except when the heater-cooler is involved, then it can be contaminated by the heater-cooler.

A. I --

Again, I think that's the implication of the FDA alert.

Q. I mean you're citing it. Do you agree with it or not?

A. Yes.

Q. Okay.

A. Yeah.

Q. So -- so a wound could be contaminated by airborne contamination.

A. Right.

Q. Okay.

A. A -- a wound -- a wound can.

Q. Okay. I mean that's why you have unidirectional flow or laminar flow and filters and HVAC systems, to provide the cleanest air possible at the OR; correct?

A. Yes.

Q. I mean that's why you have positive pressure

in the OR; correct?

A. Yes. Yes.

Q. To keep contaminants out.

A. To keep contaminants out. What the relative risk of those contaminants are in surgical in -- infections is less clear. As I said, the -- what I have been taught is that it is about the skin -- skin and subcutaneous flora as the source of surgical contamination. And while it may be possible that the air is a contributor, I am unable to describe its relative contribution and therefore risk.

Q. But you're basing this on what you were taught 25 years ago and not on any scientific journal or article at -- at this point in time.

MS. LEWIS: Objection, form.

A. I'm base -- basing it on what is -- has been taught continually since -- since my training.

Q. But you're not an infectious disease expert; correct?

A. I'm not an --

Q. Okay.

A. -- infectious disease expert.

Q. And you've never studied or researched the causes of periprosthetic joint infections; correct?

A. Correct.

MS. LEWIS: Okay. Gabe, is this a good time for a break or --

MR. ASSAAD: Couple minutes on the warning.

BY MR. ASSAAD:

Q. The only warning that you're referring to is the hosing warning in your report; correct?

Page six.

A. Well I can -- I can -- I can read it to you, but it does comment on the hosing -- hosing warning and says -- it says that with respect to risk of contamination or infection, that I don't believe a warning -- a warning was warranted.

Q. Okay. But you're not an infectious disease expert; correct?

A. I am not an infectious disease expert.

Q. And you don't know what concerns orthopedic surgeons have with particles; do you?

A. I can't speak for orthopedic --

Q. Okay.

A. -- orthopedic surgeons.

Q. And you've never ever once in your life created any type of warning for a medical device; correct?

A. Correct.

Q. And you offer that opinion without having

seen the warnings provided on the original device, the 200 series, the 500 model, or the 700 series; correct?

A. I'm sorry?

Q. You haven't seen the warnings on any of the devices besides the 505.

A. That's probably true.

Q. Okay. You haven't looked at the operating room man -- operating manual; correct?

A. Not since -- not since they first originally put them into use.

Q. You haven't looked at any of the warnings of any other forced-air warming devices; have you?

A. I haven't seen in person any other forced-air warming devices.

Q. You haven't looked at the 510(k); have you?

A. No.

MR. ASSAAD: Okay. Let's take a break.

THE REPORTER: Off the record, please.

(Recess taken.)

BY MR. ASSAAD:

Q. Doctor, are you aware that the 1996 -- 1996 Kurz study was funded by Augustine?

A. I'm not aware of that.

Q. Would that affect your interpretation of -- or -- or your opinion of the 1996 article?

A. I'm unable to comm -- comment on Dr. Reed's competence as a researcher.

Q. So besides doing a literature review in your expert report, Exhibit No. 3, what methodology did you use to come up with your conclusions on pages six and seven?

A. I looked at the literature, including the systematic rev -- reviews, and my own clinical experience.

Q. Okay. I said besides the literature what did you do. Just your own clinical experience?

A. Yes. I did not undertake any primary research.

Q. So what in your clinical experience that you did to indicate that maintaining normothermia improves outcomes in surgical patients?

A. That I don't see pa -- patients often -- often shiver, that I don't see pa -- patients who are warm -- warm become dangerously hypertensive, and that I believe that the rate of surgical infect -- infections is at least at bench -- benchmark or better.

Q. Well you don't follow patients after they leave the PACU on a regular basis; do you?

A. No.

Q. Okay. And if they did get a surgical-site infection, such as a superficial wound infection that didn't -- that didn't require surgery, that you wouldn't know about it; would you?

A. I would -- I -- I would not perhaps know about an individual patient, but in aggregate the performance of our surgical service I would be aware of.

Q. By the data.

A. By the -- by the data or by our tracking.

Q. But what have you done, I mean clinically, to show that maintaining normothermia improves the outcomes in surgical patients? What tests have you done? What data have you looked at?

A. I've looked -- looked at -- I -- I've looked -- looked at my -- my own patients and I've looked at the aggregate da -- data from our institution against various -- against various benchmarks.

Q. That could have been caused --

A reduction in infection rates could have been caused by skin prep; right?

A. It could be. All -- all of these things have many -- many cause -- many causes.

Q. It could have been caused by prophylactic

antibiotics' timing; correct?

A. It could -- it could have.

Q. So what have you done in your clinical practice to show that maintaining normothermia improves the outcome in surgical patients?

MS. LEWIS: Objection, asked and answered.

A. As I said, the -- the --

In aggregate, I can look at the rate of surgical infections in my institution being at -- at benchmark or bett -- or better, and I look at the -- at the literature and in particular the systematic reviews.

Q. Take the literature out of it.

A. Well the literature is --

Q. Take the lit --

I'm saying in your clinical practice, what have you done to say, "Aha, maintaining normothermia reduces the incidence of surgical-site infection?"

A. I would say maintaining normother -- normothermia is one of a number of practices that lead to that, and we adhere closely enough to those practices to produce good results.

Q. If you have prophylactic antibiotics, skin prep, HVAC system, surgical procedure and technique, okay, and maintaining normothermia, and you have an

infection rate that meets benchmark or a little bit better, how did you determine that this one, maintaining normothermia, had an effect on surgical patients -- outcomes of surgical patients and the other four --

A. I didn't say that the other four didn't.

Q. Okay. So it may -- it may or may not have an effect. You don't know; do you?

A. So on the -- on -- on the basis of my person -- of my personal exper -- experience, I have not done a study to isolate temperature management from other techniques to optimize patient outcomes.

Q. So you're solely relying on the literature to support --

A. I am principally relying on the -- on the literature.

Q. Solely relying on the literature.

MS. LEWIS: Objection, misstates the testimony.

A. No, I -- I disa -- I disagree. I look at --

If -- if our performance on infections or other important complications, cardiovascular mortal -- morbidity and -- and so forth, were outliers, then I would be looking at are we maintaining normothermia, are we giving antibiotics at

the -- and -- and -- and take it apart. So I fully recognize that these things are all multifactorial.

Q. If I ask you to give me evidence outside the literature in your clinical practice that indicates maintaining normothermia im --

A. In isolation?

Q. -- improves outcomes in surgical patients in your clinical practice, --

A. No.

Q. -- what evidence do you have?

A. If you're talking about that as the sole factor?

Q. Yes.

A. No.

Q. Okay. You have none; correct?

A. Correct.

Q. Okay. Going to page four, halfway through you write, "The opinions of plaintiffs' experts Drs. Stonnington and Jarvis largely rely on this entirely unproven relationship. In addition, these experts also attribute the alleged risk of the Bair Hugger device to the bacterial content of the internal and external surfaces of the device and the output of the Bair Hugger hose."

Did I read that correctly?

A. My credentials have no -- say nothing -- say nothing about the bacterial load. I'm not sure how my credentials could say anything about the bacterial load or --

Q. I'm just asking. So you agree with me that there's nothing --

A. My creden -- my credentials say something --

Q. Your experience. Experience, education, training.

A. Okay.

Q. What about your experience, education, training, about you, doctor, gives you the expertise to determine whether or not the Bair Hugger has any effect on the airflow that could increase the bacterial load over the surgical site?

MS. LEWIS: Asked and answered.

A. I have said multiple times that I am not an expert in bacterial load over the -- over the surgical site.

Q. So I'm just trying to figure out --

Forget about the literature. Without the literature, you actually have no methodology to offer the opinion that the Bair Hugger does not increase the bacterial load over the surgical site and is safe.

MS. LEWIS: Objection, form.

A. Without the literature.
Q. Without the literature.
A. That's -- that's -- that's corr -- correct. I've already said that.
MR. ASSAAD: Okay. That's all I have. Thank you.
MS. LEWIS: We'll switch place -- places.
THE REPORTER: Off the record, please.
(Discussion off the record.)

REDIRECT EXAMINATION

BY MS. LEWIS:
Q. Dr. Hannenberg, you were asked questions about a study called Darouiche and you mentioned that you had not seen that study and that study wasn't presented for you to review today; correct?
A. That is correct.
Q. Did Mr. Assaad mention to you that -- in that study, whether the Bair Hugger was even studied in that study?
A. I think he said that the Bair Hugger increased bacterial load and infections.
Q. But did he tell you --
MR. ASSAAD: Objection, misstates.
Q. But did he tell you that the Bair Hugger was even tested in that study? I mean do you even know if

A. I -- I read it some time -- some time ago and I need to refresh my memory.

Q. You prepared for today's deposition; correct?

A. Yes.

Q. You spent about 15 hours in preparation of today's deposition.

A. Well if you say -- if you say.

Q. Well that's what -- that's what you said. You approximated 15 hours since June 15th and today in preparation of today's deposition.

A. Okay.

Q. How did you prepare? Did you look at the studies in preparation?

A. I looked at -- I looked at some of the studies. I did not look -- apparently look at all of the studies.

Q. Okay. Did you look at the underlying CFD analysis Memarzadeh did that -- in that letter to the editor?

A. In most of these instances, as I -- as I've said, my expertise in statistical analysis and methodologic design puts me in a position where I re -- rely on methodol -- methodologists and -- and editorial boards.

Q. So you're relying on Memarzadeh on a CFD study that you don't even understand; isn't that correct?

A. I am relying on the conclu -- the conclusion that he and -- he drew.

Q. But you're not an engineer. You don't understand the methodology he used, do you, to come to that conclusion? Do you?

A. Well if he is rep -- repre --

Q. "Yes" or "no." Do you understand the CFD analysis?

MS. LEWIS: Stop interrupting him, Gabe.

Q. "Yes" or "no."

A. Do I --

No. That is not my expertise, --

Q. Do you know what the Navier-Stokes equations are?

A. -- that's correct.

Q. Do you know what the Navier-Stokes equations are?

A. No, I don't.

Q. Okay. So you just take the conclusions of Memarzadeh without even understanding how he got to his conclusions; do you? Isn't that correct?

A. Correct.

Q. No. They're just saying there's not enough evidence at this point in time.

A. No, they did --

Q. Okay.

A. -- they did not say that.

Q. Okay. International Concensus says further research is warranted. Are you aware of that?

A. Yes.

Q. Okay. ECRI says they're going to monitor it; correct?

A. Yes.

Q. Okay.

(Discussion off the stenographic record.)

Q. Do you even acknowledge there's a theoretical risk that the Bair Hugger can cause a surgical-site infection?

MS. LEWIS: Objection to form.

A. I know no basis for that theory.

Q. So even though the International Concensus has a basis for that statement, you have no basis.

A. I --

Correct, I have no -- I have no basis.

MR. ASSAAD: That's all I have.

THE REPORTER: Anything further?

MS. LEWIS: No.

C E R T I F I C A T E

I, Richard G. Stirewalt, hereby certify that I am qualified as a verbatim shorthand reporter, that I took in stenographic shorthand the deposition of ALEXANDER A. HANNENBERG at the time and place aforesaid, and that the foregoing transcript is a true and correct, full and complete transcription of said shorthand notes, to the best of my ability.

Dated at Deerwood, Minnesota, this 14th day of August, 2017.

RICHARD G. STIREWALT
Registered Professional Reporter
Notary Public